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| 10/520,065 | 09/13/2005 | Heinz Von Der Kammer | 37998-237382 | 5124 |

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| EXAMINER | |
|---|---|
| CHERNYSHEV, OLGA N | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/520,065 | VON DER KAMMER ET AL. | |
| | Examiner | Art Unit | |
| | Olga N. Chernyshev | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-8,10-16 and 20-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 17-19, 24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. Claims 9, 17, 19 and 24-25 have been amended as requested in the amendment filed on December 05, 2007. Following the amendment, claims 1-25 are pending in the instant application.

Claims 1-8, 10-16 and 20-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 30, 2007.

Claims 9, 17-19, 24 and 25 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on December 05, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### *Specification*

4. On a separate page identified as "Amendment to the specification", Applicant presents arguments regarding the proper format of sequence identifiers. Specifically, Applicant submits "that the format in the MPEP is SEQ ID No." and not the format "SEQ ID NO:" the Examiner has recommended". For clarification, the appropriate section of MPEP pertained to the requirements for sequence identifiers is cited below:

" MPEP 2422.03 The Requirements for a Sequence Listing and Sequence Identifiers; Sequences Embedded in Application Text; Variants of a Presented Sequence.

37 CFR 1.821(c) requires that applications containing nucleotide and/or amino acid sequences that fall within the above definitions, contain, as a separate part of the disclosure on paper or compact disc, a disclosure of the nucleotide and/or amino acid sequences, and associated information, using the format and symbols that are set forth in 37 CFR 1.822 and 37 CFR 1.823. This separate part of the disclosure is referred to as the "Sequence Listing." The "Sequence Listing" submitted pursuant to 37 CFR 1.821(c), whether on paper or compact disc, is the official copy of the "Sequence Listing."

37 CFR 1.821(c) requires that each sequence disclosed in the application appear separately in the "Sequence Listing," with each sequence further being assigned a sequence identification number, referred to as "SEQ ID NO." The sequence identifiers must begin with 1 and increase sequentially by integers. The requirement for sequence identification numbers, at a minimum, requires that each sequence be assigned a different number for purposes of identification. However, where practical and for ease of reference, sequences should be presented in the separate part of the application in numerical order and in the order in which they are discussed in the application".

The text of the instant specification, including drawings and currently amended claims remains not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03). Appropriate correction is required.

### *Claim Rejections - 35 USC § 101*

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 9, 17-19, 24 and 25 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record in section 4 of Paper mailed on April 27, 2007. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or the significance of binding this protein to a specific physiological function or a clinical condition.

Applicant traverses the rejection on the premises that "[t]he specification teaches that the TB2 gene is differentially expressed in samples from patient's suffering from AD when compared to healthy subjects. For example, the specification shows in Table 1 and the description of Table 1 that subtractive suppressive microarray hybridization comparing healthy control persons with AD patients revealed that the TB2 gene was differentially expressed in the two groups. This differential expression is further shown using quantitative RT-PCR. See figures 2 and 3 and description thereof" (p. 11 of the Response). Applicant further submits that "[t]he use of TB2 as a screening target is also disclosed in the specification at page 17 (bottom) through page 20. Thus, the pending claims directed to ligand binding assays utilizing TB2 as a marker and/or screening target have a substantial and credible utility in detecting and treating neurodegenerative diseases like AD, as indicated in the specification" (pp. 11-12). Applicant's arguments have been given careful consideration but are not persuasive for the following reasons.

The instant claims are drawn to an assay for testing a compound for inhibition of binding between a ligand and TB2 protein of SEQ ID NO: 1. As fully explained in the previous office

action of record, the biological function of TB2 protein of SEQ ID NO: 1 is currently unknown or not disclosed. The specification fails to present any evidence that TB2 protein of SEQ ID NO: 1 plays any specific physiological role in the etiology of Alzheimer's disease or any neurodegenerative process in general. This alone is not probative of lack of utility under 35 U.S.C. § 101, but is merely one of the analyses, which must be made. While not required by any statute or rule, if Applicant had disclosed a biological role or function of the TB2 protein, such might support a disclosed utility, such as for diagnosis or treatment of disease. In the instant case, the factual information presented in the disclosure is limited to differential expression of the protein, TB2 protein of SEQ ID NO: 1, in different areas of AD brain as compared to normal control. The data are presented as ratio, see Table 1, for example. However, the instant claims are directed to assays to test compounds for inhibition of binding between an unidentified ligand and the protein of SEQ ID NO: 1. The specification discloses finding of differential expression of TB2 protein of SEQ ID NO: 1 in brain tissue of patients with AD but discloses no utilities based on detection of binding between a compound, "a ligand" and the TB2 protein of SEQ ID NO: 1, as currently claimed. In the absence of knowledge of the biological significance of the process of binding between "a ligand" and TB2 protein of SEQ ID NO: 1 or the relevance of inhibition of this process to AD diagnosis or therapy, there appears to be no immediately obvious patentable use for the instant claimed invention. For example, if the worker of skill in the art identified a compound as capable of inhibiting binding, what would that mean with respect to diagnosis of Alzheimer's? Or to the clinical use of the compound? Since the instant claims fail to recite any steps related to an individual suffering from AD (obtaining samples, analyzing pattern of distribution etc.), the claims, as currently presented, are limited only to assessment of binding

between random compounds, unknown ligands and the protein of SEQ ID NO: 1. The Examiner maintains that in the absence of knowledge of significance of this process of binding, the instant assay clearly encompasses using protein of SEQ ID NO: 1 as the object of further research, which is prohibited by the Supreme Court decision of *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966). The *Brenner* Court held that "[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

Thus, for reasons of record fully explained earlier and reasons above, the instant rejection is maintained.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 9, 17-19, 24 and 25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9. Claims 9, 17-19, 24 and 25 further stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in section 7 of Paper mailed on April 27, 2007. It is noted that Applicant's Response did not acknowledge this ground of rejection, which is not fully responsive for failing to comply with 37 CFR 1.111 (b). Reply by applicant or patent owner to a non-final Office action.
(b) In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to the Office action. The reply by the applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner 's action and must reply to every ground of objection and rejection in the prior Office action. MPEP 714.02.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 9, 17-19, 24 and 25 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claims 9, 17-19 and 24 stand vague and indefinite for recitation of "a ligand". Applicant submits that "this term means any ligand that binds to TB2" However, under this interpretation, this term is not adequate with the art-recognized meaning of "a ligand". For example, could an atom, or a metal, ion be a ligand? The specification does not identify this instant TB2 as a receptor; therefore, could any antibody, of different species perhaps, qualify as a

ligand? To identify the nature of "a ligand" in the context of the claimed method is especially important because the steps specifically require "adding a detectable, labeled ligand" and it is currently not obvious as what a skilled practitioner is suppose to add in order to practice the invention.

13. Also Claim 9, as currently amended, is indefinite for recitation "using the measured amounts [...] to determine". Applicant is advised that claim 9 is directed to an assay/process comprising the step of "using" without setting forth any steps involved in the process of "using", and therefore it is unclear what process Applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

14. Claim 25 is indefinite for being dependent from indefinite claim.

***Conclusion***

15. No claim is allowed.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

February 20, 2008

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649